

# UPDATE

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## **FDA Approves New Drug to Treat Type 1 and Type 2 Diabetes**

The Food and Drug Administration (FDA) approved Symlin, an injectable medicine to control blood sugar for adults with type 1 and type 2 diabetes. Symlin is to be used in addition to insulin therapy in patients who cannot achieve adequate control of their blood sugars on intensive insulin therapy alone.

Symlin will be the only therapy for the treatment of type 1 diabetes other than insulin. Patients with type 2 diabetes already have several other types of oral therapies available. The safety and efficacy of Symlin were studied in approximately 5000 patients. Overall Symlin therapy was associated, in patients with both types of diabetes, with improvements in the control of blood glucose and with weight loss. So-called "tight" control of blood sugar is desirable in all patients with diabetes in order to reduce risks for long-term adverse consequences of the disease, including blindness, kidney disease, and vascular disease.

Symlin is to be used only in combination with insulin to help lower blood sugar during the 3 hours after meals. Symlin will have a Medication Guide (FDA-approved patient labeling) and a Risk Minimization Action Plan (RiskMAP) due to areas of concern. First, the principle risk associated with Symlin therapy is hypoglycemia, and this risk is greatest in patients with type 1 diabetes and in patients with gastroparesis (motility problems of the stomach—a long-term complication of diabetes). Second, the potential for medication errors, specifically mixing of Symlin with insulin in the same syringe, which can alter the activity of the insulin, is addressed in the Medication Guide and in physician labeling. Finally, the potential for off-label use in patients where the benefit/risk profile has not been characterized or demonstrated is also a concern and will be monitored by the sponsor.

The Medication Guide informs patients that Symlin should only be used if they are already using their insulin as prescribed, but still need better blood sugar control; will follow their doctor's instructions exactly; will follow-up with their doctor often; will test their blood sugar levels before and after every meal, and at bedtime; and understand how to adjust Symlin and insulin doses.

Symlin should not be used if patients cannot tell when their blood sugar is low, have gastroparesis (slow stomach emptying), or are allergic to pramlintide acetate, metacresol, D-mannitol, acetic acid, or sodium acetate.

Side effects associated with Symlin include but are not limited to nausea, vomiting, abdominal pain, headache, fatigue and dizziness.

Please visit [www.fda.gov](http://www.fda.gov) for more information about Symlin.

